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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Zou et al.

Application No.: 09/122,427

Art Unit: 1615

Filed: July 24, 1998

Examiner: Kishore, G.

For: SUBMICRON LIPOSOME
SUSPENSIONS OBTAINED FROM
PRELIPOSOME LYOPHILATES

Attorney Docket No.: UTSC-584
P&E Ref: 8449-205

DECLARATION OF ROMAN PEREZ-SOLER UNDER 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, ROMAN PEREZ-SOLER do declare and state:

1. I am presently Chairman of the Department of Oncology at the Montefiore Medical Center, Bronx, New York.
2. My academic and technical experience, honors and a list of publications are set forth in my *Curriculum Vitae*, attached hereto as **Exhibit A**.
3. I have read and am familiar with U.S. Application No. 09/122,427 filed July 24, 1998 (the '427 application), which I understand is a continuation of U.S. Application No. 08/468,791 filed June 6, 1995, now U.S. Patent No. 5,902,604 issued May 11, 1999. I am a co-inventor of the subject matter disclosed and claimed in the '427 application together with Yiyu Zou and Waldemar Priebe.

4. I have been informed by patent counsel for the subject application that certain claims have been rejected in an October 23, 2001 Office action as allegedly anticipated or obvious in view of certain references cited by the Examiner.

5. I have read and am familiar with the October 23, 2001 Office action and the cited references where the allegations of paragraph four above are made. I am submitting this Declaration because I do not agree with the Examiner's conclusions that the claims are anticipated or obvious in view of the references cited. Accordingly, the following remarks are provided in support of the patentability of the claimed invention.

6. I understand that the Examiner rejected certain claims as allegedly anticipated by Mehta et al., U.S. Patent No. 4,950,432 or Mehta et al., U.S. Patent No. 5,811,119 (collectively "*Mehta*"), asserting that *Mehta* anticipates the claimed invention by disclosure of preliposomal powders containing a drug and a mixture of phospholipids. I understand further that the Examiner rejected the remaining claims as allegedly obvious over *Mehta* in view of Unger et al., U.S. Patent No. 5,585,112 ("*Unger*"), Isliker et al, U.S. Patent No. 5,089,602 ("*Isliker*") or Hsu, U.S. Patent No. 5,653,996 ("*Hsu*"), individually or in combination, because *Unger*, *Isliker* and *Hsu* each make certain disclosures regarding liposomes and surfactants. Finally, I understand that the claims have been amended such that all claims now require the presence of a non-lipid surfactant in a lyophilate of the invention.

7. In my opinion, none of the cited references alone or in combination teach or suggest making a preliposome-lyophilate by using a small amount of a non-lipid surfactant such as Tween in order to provide the properties of fast and convenient reconstitution upon addition of aqueous solution. The lyophilates of the invention containing such a surfactant

have been tested (*see* pages 19-28 of the '427 application) and found to have a surprising ability to form liposomes very rapidly and conveniently, *i.e.* in about one minute with only hand-shaking. Moreover, liposomes reconstituted from such a lyophilate have a surprisingly small and useful average diameter of less than about 400 nm. In my opinion, such a lyophilate is not disclosed or suggested by the very disparate teachings in the references cited by the Examiner.

8. I declare that all statements made in this Declaration of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated:

4/17/02



Roman Perez-Soler

Attachment:

Exhibit A: *Curriculum Vitae* of Roman Perez-Soler